

## **REMARKS**

The applicants acknowledge the Office Action of May 2, 2007, with appreciation. Claims 34, 36-38, 41-43, 49-51 and 55-72 are pending in the application, of those, Claims 36, 37 and 55-71 are withdrawn from consideration. Claims 34, 38, 41-43, 49-51 and 72 are presently under examination.

### **INDEFINITENESS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH:**

The Office rejects Claims 34, 38, 41-43, 49-51 and 72 under 35 U.S.C. § 112, second paragraph, for indefiniteness. The Office basis for the rejection of the claims is for the term "close to" which defines the claimed Th1 response. The Office notes that the specification attempts to define the term "close to"; however, the Office concludes that the definition in the specification does not accurately define the limits of the Th1 response in relation to the Th2 response.

With the instant Response, Claims 34 and 72 are amended to more precisely define the Th1 response and include the language, "the Th1 response is at least 0.5 times the Th2 response" to define the claimed mixed Th1/Th2 response. Support for this language may be found in the Specification at page 3, beginning at line 32.

Furthermore, the Office rejects Claim 49 for failing to claim with particularity, specifically for the term "carries".

Claim 49 is presently amended to add clarifying language and to incorporate the embodiments presently recited in Claim 51, which embodiments define the agent which "carries" the membrane fraction. Claim 51 is hereby canceled as being redundant on amended Claim 49.

The Applicants submit that the instant amendment provides the requested definition, thereby obviating the rejection for failing to claim with particularity. Reconsideration and withdrawal of the rejection is respectfully requested.



Moving on, the Office maintains the rejection of Claims 34, 38 and 72 under 35 U.S.C. § 102(b) as being anticipated by Rauly, et al. (Research in Immunology, Vol 149 No. 1, page 99, Jan. 1998). The Office concludes that Rauly, et al. disclose a mixed Th1/Th2 response, wherein the Th1 response is "close to" the Th2 response.

With the instant amendment, the claims are drawn to a mixed Th1/Th2 response wherein, "the Th1 response is at least 0.5 times the Th2 response". Moreover, Claim 34 is amended to clarify that the *Klebsiella pneumoniae* membranes are recovered following the lysing step, thereby distinguishing the instant crude membrane preparation from the purified *Klebsiella pneumoniae* OmpA protein disclosed in the cited art.

The Applicants submit that Rauly, et al. do not anticipate the instant claims drawn to membranes recovered following lysis of *Klebsiella pneumoniae* bacteria because Rauly, et al. disclose a recombinant P40 protein which is purified from *E. coli*, and which purified P40 protein is materially distinct from a membrane fraction obtained from *Klebsiella pneumoniae* bacteria as claimed herein. Furthermore, Rauly, et al. do not disclose a mixed Th1/Th2 response in which the Th1 response is at least 0.5 times the Th2 response, as defined in the instant claims. Rauly, et al. disclose that a mixed Th1/Th2 response is elicited by a recombinant P40 carrier protein; however, the magnitude of the Th1 response relative to the Th2 response is not disclosed. The Applicants submit that the purified P40 carrier protein does not provide a Th1 response which is at least 0.5 times the Th2 response, which understanding is supported by the cited Binz, et al. disclosure of a purified OmpA (P40) carrier protein/antigen induced mixed immune response which is outside the scope of the instant claims, which will be discussed in more detail below.

Consequently, the Applicants submit that Rauly, et al. do not meet the claim limitations of a *Klebsiella pneumoniae* membrane fraction which induces an immune response to an antigen, wherein the Th1 response is at least 0.5 times the Th2 response. Therefore, Rauly, et al. may not support a rejection for anticipation.



Reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b) is respectfully solicited.

The Office maintains the rejection of Claims 34, 38, 41, 43, 49 and 72 under 35 U.S.C. § 102(e) as being anticipated by Binz, et al. (U.S. Patent No. 6,197,929). The Office concludes that Binz, et al. disclose a mixed Th1/Th2 response, wherein the Th1 response is “close to” the Th2 response.

The claims are presently amended to clarify that *Klebsiella pneumoniae* membranes are recovered following the lysing step, thereby distinguishing the instant crude membrane fraction from a purified *Klebsiella pneumoniae* OmpA protein preparation as described in the art.

The Applicants further distinguish and clarify that the instantly claimed membrane fraction, which membranes are recovered following lysis of *Klebsiella pneumoniae* bacteria, is materially distinct from a purified OmpA (P40) membrane protein disclosed in Binz, et al. This distinction is substantiated by the Binz, et al. disclosure of membrane protein extracts which are contaminated with lipids and lipopolysaccharides (LPS) (Column 1, lines 30-33; Example 1 and Table 1) and teaching of further purification of OmpA (P40) to homogeneity (Column 4, lines 66-67). This teaching supports the understanding that the purified OmpA (P40) carrier protein of Binz, et al. is materially distinct from the instant *Klebsiella pneumoniae* crude membrane fraction, and therefore, Binz, et al. do not teach the instant *Klebsiella pneumonia* membrane fraction as claimed.

Furthermore, Binz, et al. do not disclose a *Klebsiella pneumoniae* membrane fraction admixed with an antigen or a hapten, which is administered to provide a mixed Th1/Th2 response wherein the Th1 response is at least 0.5 times the Th2 response. The Applicants note specifically the disclosure of Binz, et al., at Table 4, in which a mixed Th1/Th2 response is elicited by administering OmpA (P40) coupled with an antigen; however, the Th1 response is substantially lower than the Th2 response.



Consequently, Binz, et al. teach a purified OmpA (P40), which purified OmpA provides a mixed Th1/Th2 type response which is outside the scope of the claimed immune response, that is, a Th1 response which is at least 0.5 times the Th2 response. Moreover, this teaching extends to the Rauly, et al. disclosure of a mixed Th1/Th2 response which is elicited by administering a purified OmpA (P40) protein, and supports the understanding that Rauly, et al. do not disclose a mixed Th1/Th2 type response in which the Th1 response is at least 0.5 times the Th2 response, as claimed.

Consequently, claims drawn to a *Klebsiella pneumoniae* membrane fraction which is effective in inducing an immune response toward a mixed Th1/Th2 type response, in which the Th1 response is at least 0.5 times the Th2 response, are not anticipated by the cited Rauly, et al. and Binz, et al. Reconsideration and withdrawal of the rejection for anticipation is respectfully solicited.

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Accordingly, entry of the present amendment, reconsideration of all grounds of rejection, withdrawal thereof and passage of this application to issue are all thereby respectfully solicited.

It should be apparent that the undersigned attorney has made an earnest effort to place this application into condition for immediate allowance. If he can be of assistance to the Examiner in the elimination of any possibly-outstanding insignificant impediment to an immediate allowance, the Examiner is invited to call him at his below-listed number for such purpose.

Allowance is solicited.

Respectfully submitted,

THE FIRM OF HUESCHEN AND SAGE

By:   
G. PATRICK SAGE, Attorney #37,710



Dated: July 27, 2007  
Customer No.: 25,666  
Seventh Floor, The Kalamazoo Building  
107 West Michigan Ave.  
Kalamazoo, MI 49007  
(269) 382-0030

Enclosure: Listing of Claims, and Postal Card Receipt

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